

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently amended) An implantable cardiac ~~lead~~-system, comprising:

- a ~~lead body comprising a rigid elongated support structure;~~
- a cardiac electrode ~~supported by the lead body,~~ the electrode configured for subcutaneous, ~~non-intrathoracic~~ placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;
- ~~an implantable can coupled to the lead body, the rigid elongated support structure of the lead configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient;~~
- ~~one or more conductors coupled to the cardiac electrode and disposed within the lead body;~~
- a pharmacological agent provided along an exterior surface of the implantable cardiac system ~~along at least a longitudinal portion of an exterior surface of the lead body;~~
- and
- a driving arrangement coupled to the ~~can-lead,~~ the driving arrangement comprising a polyvinylidene fluoride layer and a conducting surface coating along the polyvinylidene fluoride layer, the driving arrangement configured to provide sonophoresis delivery of a pharmacological agent from the exterior surface along which the pharmacological agent is provided ~~longitudinal portion of the exterior surface of the lead body~~ to subcutaneous tissue by electrical activation of the conducting surface coating causing movement of the polyvinylidene fluoride layer.

2. (Currently amended) The ~~lead~~-system according to claim 1, further comprising a rigid elongated support structure coupled to the can, wherein the cardiac electrode is provided on the rigid elongated support structure ~~lead body and the implantable can form a unitary structure having an arcuate shape.~~

3. (Currently amended) The ~~lead~~-system according to claim ~~1~~2, wherein the rigid elongated support structure is configured to maintain the cardiac electrode and a second electrode on the can in opposition with respect to the ventricles of the heart.

4. (Currently amended) The ~~lead~~-system according to claim 1, wherein the polyvinylidene fluoride layer and the conducting surface coating are provided along the can and the driving arrangement is configured to provide sonophoresis delivery of the pharmacological agent from the can along the longitudinal portion of the exterior surface of the lead body.

5. (Currently amended) The ~~lead~~-system according to claim 1, further comprising an implantable pharmacological agent reservoir within the can, wherein the lead body further comprises a lumen in fluid communication with the reservoir configured to facilitate transport of pharmacological agent stored in the reservoir through the lead.

6. (Currently amended) The ~~lead~~-system according to claim 5, further comprising a micro-pump configured to facilitate transport of pharmacological agent from the reservoir through the lumen to the exterior surface of the implantable cardiac system along which the pharmacological agent is provided of the lead body.

7. (Currently amended) The ~~lead~~-system according to claim 1, wherein the driving arrangement is configured to generate an acoustic field that impels the pharmacological agent into subcutaneous, ~~non-intrathoracic~~ tissue.

8. (Currently amended) The ~~lead~~-system according to claim 1, wherein the pharmacological agent is disposed along the conducting surface coating.

9. (Currently amended) The ~~lead~~-system according to claim 1, wherein at least part of the driving arrangement comprises an external driver detachably coupled to the can ~~lead system~~, the external driver configured to provide power and control for phoresis delivery of the pharmacological agent during surgical implantation of the implantable cardiac system ~~lead-body~~.

10. (Currently amended) The ~~lead~~-system according to claim 1, wherein the driving arrangement is configured to generate an ultrasonic field that drives the pharmacological agent into subcutaneous, ~~non-intrathoracic~~ tissue.

11. (Currently amended) The ~~lead~~-system according to claim 1, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy.

12. (Currently amended) The ~~lead~~-system according to claim 1, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent before delivery of electrical cardiac stimulation therapy.

13. (Currently amended) The ~~lead~~-system according to claim 1, wherein the pharmacological agent is disposed in a coating provided along a the longitudinal portion of the exterior surface of the lead body coupled to the can and the driving arrangement is configured to provide sonophoresis delivery of the pharmacological agent from the lead body.

14. (Currently amended) The ~~lead~~-system according to claim 1, wherein the pharmacological agent is disposed on the polyvinylidene fluoride layer-rigid elongated support structure has a mechanical memory such that the lead body retains a configuration after being shaped by a clinician under manual force and generally retains the configuration after implantation.

15. (Currently amended) The ~~lead~~-system according to claim 1, wherein the exterior surface along which the pharmacological agent is provided is a portion of the exterior surface of the can-driving arrangement is configured to deliver a DC voltage to the conducting surface coating to provide sonophoresis delivery of the pharmacological agent.

16. (Currently amended) The ~~lead~~-system according to claim 1, wherein the driving arrangement is configured to deliver an AC signal alternating at an ultrasonic frequency to the conducting surface coating to provide sonophoresis delivery of the pharmacological agent.

17. (Currently amended) The ~~lead~~-system according to claim 1, wherein the driving arrangement is configured to deliver a DC bias voltage with an AC signal alternating at an ultrasonic frequency to the conducting surface coating to provide sonophoresis delivery of the pharmacological agent.

18. (Previously presented) An implantable system, comprising:

a lead, comprising:

a lead body; and

a cardiac electrode coupled to the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

a can coupled to the lead;
a pharmacological agent provided on a portion of an exterior surface of the can; and
a driving arrangement coupled to the can, the driving arrangement comprising a polyvinylidene fluoride layer and a conducting surface coating along the polyvinylidene fluoride layer, the driving arrangement configured to provide sonophoresis delivery of the pharmacological agent from at least the portion of the exterior surface of the can to subcutaneous tissue by electrical activation of the conducting surface coating and movement of the polyvinylidene fluoride layer.

19. (Previously presented) The system according to claim 18, wherein the driving arrangement is configured to generate an acoustic field that impels the pharmacological agent into subcutaneous, non-intrathoracic tissue.

20. (Previously presented) The system according to claim 18, wherein the driving arrangement is configured to generate an ultrasonic field that drives the pharmacological agent into subcutaneous, non-intrathoracic tissue.

21. (Previously presented) The system according to claim 18, further comprising an implantable pharmacological agent reservoir and a micro-pump configured to facilitate transport of pharmacological agent from the reservoir to the exterior surface of the can.

22. (Previously presented) The system according to claim 18, wherein the pharmacological agent is disposed along the conducting surface coating.

23. (Previously presented) The system according to claim 18, wherein the at least part of the driving arrangement comprises an external driver detachably coupled to the can, the external driver configured to provide power and control for phoresis delivery of the pharmacological agent during surgical implantation of the can.

24. (Canceled)

25. (Previously presented) The system according to claim 18, wherein the can comprises a porous region on the portion of the exterior surface, the pharmacological agent at least partially filling pores of the porous region.

26. (Original) The system according to claim 25, wherein the porous region comprises a doped polymer matrix.

27. (Previously presented) The system according to claim 18, further comprising a lead body coupled to the can, the lead body and the can forming a rigid unitary structure having an arcuate shape.

28. (Original) The system according to claim 27, wherein the coating covers at least 25% of a surface area of the can.

29. (Previously presented) The system according to claim 18, further comprising a lead coupled to the can, the lead comprising an electrode and a rigid elongated support structure configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient.

30. (Previously presented) The system according to claim 18, wherein the polyvinylidene fluoride layer and the conducting surface coating are provided along the exterior surface of the can.

31. (Previously presented) The system according to claim 18, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative

to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy.

32. (Previously presented) The system according to claim 18, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates phoresis delivery of the pharmacological agent before delivery of electrical cardiac stimulation therapy.

33-47. (Canceled)

48. (Currently amended) An implantable cardiac lead system, comprising:

a lead body ~~comprising a rigid elongated support structure;~~

a cardiac electrode coupled to the lead body, the electrode configured for subcutaneous non-intrathoracic placement in a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

~~an implantable can coupled to the lead body, the rigid elongated support structure of the lead configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient;~~

one or more conductors coupled to the electrode and disposed within the lead body;

a pharmacological agent provided along one or both of the can and at least a longitudinal portion of an exterior surface of the lead body; and

~~means, coupled to the implantable lead, for impelling the pharmacological agent into subcutaneous tissue using sonophoresis from the longitudinal portion of the exterior surface of the lead body into subcutaneous non-intrathoracic tissue, wherein the impelling means comprises a polyvinylidene fluoride layer and a conducting surface coating~~

along the polyvinylidene fluoride layer, and the polyvinylidene fluoride layer and the conducting surface coating are provided along one or both of the can and the longitudinal portion of the lead body along which the pharmacological agent is provided.

49. (Canceled)

50. (Currently amended) The lead system according to claim 48, wherein the impelling means comprises means a polyvinylidene fluoride layer and a conducting surface coating along the polyvinylidene fluoride layer that provide for impelling the pharmacological agent using sonophoresis by electrical activation of the conducting surface coating causing movement of the polyvinylidene fluoride layer.

51. (Currently amended) The lead system according to claim 48, wherein the pharmacological agent, the polyvinylidene fluoride layer, and the conducting surface coating are provided along the implantable can-lead body and the implantable can form a unitary structure having an arcuate shape.

52. (Currently amended) The lead system according to claim 48, wherein the pharmacological agent, the polyvinylidene fluoride layer, and the conducting surface coating are provided along the longitudinal portion of the exterior surface of the lead body.

53. (Currently amended) The lead according to claim 48, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driving arrangement facilitates sonophoresis delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy.

54. (Currently amended) The lead system according to claim 48, wherein the lead body comprises a rigid elongated support structure configured to stabilize and maintain a spacing between the cardiac electrode and the implantable can in subcutaneous, non-intrathoracic tissue within the patient has a mechanical memory such that the lead body retains a configuration after being shaped by a clinician under manual force and generally retains the configuration after implantation.

55. (Previously presented) A system, comprising:

an implantable medical device, comprising:

a can that houses circuitry configured to provide one or both of cardiac monitoring and cardiac stimulation;

a lead coupled to the can, the lead comprising a lead body, a cardiac electrode coupled to the lead body, and one or more conductors coupled to the cardiac electrode and disposed within the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation;

a first pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body; and

a second pharmacological agent provided on a portion of an exterior surface of the can; and

a driver apparatus detachably coupled to the implantable medical device, the driver apparatus comprising a plurality of polyvinylidene fluoride layers and a plurality of conducting surface coatings each disposed along respective polyvinylidene fluoride layers of the plurality of polyvinylidene fluoride layers, the driver apparatus configured to facilitate sonophoresis delivery of at least one of the first pharmacological agent from the longitudinal portion of the exterior surface of the lead body and the second pharmacological agent from the portion of the exterior surface of the can by electrical activation of the conducting surface coatings and movement of the polyvinylidene fluoride layers.

56. (Previously presented) The system according to claim 55, wherein the lead comprises an rigid elongated support structure configured to stabilize and maintain a spacing between the cardiac electrode and the can in subcutaneous, non-intrathoracic tissue within the patient.

57. (Previously presented) The system according to claim 56, wherein the lead and the can form a unitary structure having an arcuate shape.

58. (Previously presented) The system according to claim 56, wherein the rigid elongated support structure is configured to maintain the cardiac electrode and a second electrode disposed on the can in opposition with respect to the ventricles of the heart.

59. (Previously presented) The system according to claim 55, wherein the polyvinylidene fluoride layers and the conducting surface coatings are provided at least along the longitudinal portion of the exterior surface of the lead body.

60. (Canceled)

61. (Previously presented) The system according to claim 55, wherein the driver apparatus is configured to deliver an AC signal alternating at an ultrasonic frequency to the conducting surface coatings to provide sonophoresis delivery.

62. (Previously presented) The system according to claim 55, wherein the driver apparatus is configured to deliver a DC bias voltage with an AC signal alternating at an ultrasonic frequency to the conducting surface coatings to provide sonophoresis delivery.

63. (Previously presented) The system according to claim 55, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driver apparatus facilitates phoresis

delivery of the pharmacological agent after delivery of electrical cardiac stimulation therapy.

64. (Previously presented) The system according to claim 55, further comprising a controller configured to coordinate phoresis delivery of the pharmacological agent relative to electrical cardiac stimulation therapy such that the driver apparatus facilitates phoresis delivery of the pharmacological agent before delivery of electrical cardiac stimulation therapy.

65. (Previously presented) The system according to claim 55, further comprising an implantable pharmacological agent reservoir within the can.

66. (Previously presented) The system according to claim 65, further comprising a micro-pump configured to facilitate transport of pharmacological agent from the reservoir to the exterior surface of the lead body and the exterior surface of the can.